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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,906	09/15/2003	Rong-Hwa Lin	A0871.70001US00	1268
23628 7590 06/11/2007 WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			EXAMINER GAMBEL, PHILLIP	
			ART UNIT 1644	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/662,906

Applicant(s)

LIN ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2006 and 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Applicant's Elections and Remarks, filed 11/03/2006 and 03/05/2007, are acknowledged.

The following was set forth in the Remarks filed 03/05/2007.

In response to the Restriction Requirement set forth in the Office Action mailed January 19, 2007, Applicant hereby provisionally elects Group I, claims 1-38, for continued examination. Applicant further elects the following species: (A) homo-multimeric compound that binds to at least two PSGL-1 proteins; (D) antigen binding domain of an anti-PSGL-1 antibody or a fragment thereof; psoriasis; and (A) absence of detecting the number of T cells or detecting the biological activity of the T cells before / after administration of multimeric compounds.

Similarly, for the avoidance of any possible doubt, the last paragraph on page 2 of the Response to Restriction Requirement mailed on October 31, 2006, is amended to read as follows:  
In response to the Restriction Requirement, Applicant has elected Group I, (A) homo-multimeric compound that binds to at least two PSGL-1 proteins; (D) antigen binding domain of an anti-PSGL-1 antibody or a fragment thereof; psoriasis; and (A) absence of detecting the number of T cells or detecting the biological activity of the T cells before / after administration of multimeric compounds, for examination. This election is made with traverse.

Upon a review of the Remarks, filed 11/03/2006; applicant noted certain inaccuracies and mischaracterizations of what is claimed, which appears to be responsible for the traversal in response to the Restriction Requirement and Election of Species of record (see original Restriction mailed 10/04/2006).

In order to set the Restriction properly in view of applicant's Remarks and to clarify if there is a traverse to the Restriction of record or whether the traverse was made solely to address certain inaccuracies and mischaracterizations of the original Restriction Requirement mailed 10/04/2006,

the previous Restriction has been vacated in order to set forth the Restriction herein to address applicant's remarks about certain inaccuracies and mischaracterizations.

The examiner apologizes for any inconvenience to applicant in this matter.

Claims 1-39 are pending.

2. Applicant is invited to review the claims to determine if any amendments to said claims would clarify the methods and the ingredients employed in said methods.

Also, applicant is invited to clarify whether the recitation of "binds at least two PSGL-1 proteins" is intended to simply indicate that the multimeric compounds binds two (2) PSGL-1 molecules or whether the claims encompass two types of PSGL-1 proteins.

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3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-38, drawn to methods of reducing T cell-mediated immune responses with multimeric compounds which bind PSGL-1 proteins, classified in Class 424, subclass 133.1.

II. Claim 39, drawn to a kit comprising PSGL-1-binding multimeric compounds, classified in Class 435, subclass 810.

4. Inventions II and I are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the products as claimed can be used in a materially different process such as affinity purification, detection assays, bioassays or as an immunogen.

Also, the methods of reducing T cell-mediated immune responses can be achieved a host of immunosuppressive regimens and therapeutics, other than the claimed PSGL-1-binding multimeric proteins.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-II is not required for any other group from Groups I-II and Groups I-II have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

6. *In addition to electing a Group from above,*  
this application contains claims directed to the following patentably distinct species of the claimed Groups I / II: wherein the PSGL-1-binding multimeric compound is:

- A) homomeric or
- B) heteromeric.

In addition to electing homomeric or heteromeric PSGL-1-binding compound,  
this application contains claims directed to the following patentably distinct species of the claimed Groups I / II: wherein the homomeric or heteromeric PSGL-1-binding compound comprises:

- A) P-selectin (extracellular domain),
- B) E-selectin(extracellular domain),
- C) L-selectin (extracellular domain), or
- D) an anti-PSGL-1 antibody.

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The various components of the multimeric compounds differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. The examiner notes that these molecules do not share a substantial structural feature essential to a common utility.

*If applicant elects a heteromeric compound, applicant is required to elect the components of the heteromeric compound with respect to (A) – (D) or from the disclosure of the instant specification.*

*Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06*

It is noted that the recitation of "selected from a phage library" is considered a product-by-process limitation that appears to read on any (A) – (D), though (D) may be the more appropriate species implicated

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. If applicant elects Group I from above,

and in addition to electing a particular PSGL-1 binding homomeric / heteromeric multimeric compound from Section 5 above,

this application contains claims directed to the following patentably distinct species of the claimed Group I: wherein the individual has a disease or condition selected from claims 14-18 or pages 22-23 of the instant specification.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (e.g. *psoriasis, asthma, etc.*) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

*It is noted that the election of the targeted disease will be carried over to selecting an individual being diagnosed with that elected disease as it reads on claims 14-18, if appropriate.*

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8. If applicant elects Group I from above,  
and in addition to electing a particular PSGL-1 binding homomeric / heteromeric  
multimeric compound from Section 6 above and a disease from Section 7 above,  
this application contains claims directed to the following patentably distinct species of  
the claimed Group I: wherein the methods comprise;
- A) the absence of detecting the number of T cells or detecting the biological activity  
of the T cells before / after administration of multimeric compounds,
  - B) detecting the number of T cells (e.g., see claim 20), or
  - C) detecting the biological activity of T cells (e.g. see claim 21).

These species are distinct because the methods rely upon different ingredients,  
method steps and endpoints.

*If applicant elects (C), then applicant should elect a particular biological activity of T  
cells that is detected.*

*Applicant is reminded that the amendment must point to a basis in the specification  
so as not to add any new matter. See MPEP 714.02 and 2163.06*

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for  
prosecution on the merits to which the claims shall be restricted if no generic claim is  
finally held to be allowable.

9. Applicant is advised that a response to this requirement must include an  
identification of the species that is elected consonant with this requirement, and a listing  
of all claims readable thereon, including any claims subsequently added. An argument  
that a claim is allowable or that all claims are generic is considered nonresponsive  
unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of  
claims to additional species which are written in dependent form or otherwise include all  
the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims  
are added after the election, applicant must indicate which are readable upon the  
elected species. M.P.E.P. 809.02(a).

*Should applicant traverse on the ground that the species are not patentably distinct,  
applicant should submit evidence or identify such evidence now of record showing the  
species to be obvious variants or clearly admit on the record that this is the case. In  
either instance, if the examiner finds one of the inventions unpatentable over the prior  
art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the  
other invention.*

10. Applicant is advised that the response to this requirement to be complete must  
include an election of the invention to be examined even though the requirement be  
traversed.

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11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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May 29, 2007

*Phillip Gambel*  
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*6/7/07*